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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/418,176	10/13/1999	GOUTAM DAS	1103326-0206	8505

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/418,176

Applicant(s)

DAS. GOUTAM

Examiner

Delia M. Ramirez

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 1-12, 14 and 15.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

1. Claims 1-12, 14, and 15 are pending.
2. The period for reply continues to run from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 must be timely filed to avoid abandonment of this application.
3. Applicants argue that since the previous Examiner of record stated in the final rejection (Paper No. 7, mailed on 8/28/2001) that Applicant's amendment necessitated the new grounds of rejection and at the same time the grounds of rejection were indicated to have been "explained in the previous Office Action", no new grounds of rejections were necessitated by Applicant's amendment as filed in Paper No. 6, filed on 6/15/2001, therefore the finality of the rejections should be withdrawn. These arguments have been considered but are not found persuasive for the following reasons. Claims 5-7, 10, and 14 were not examined in the first Office Action on the merits due to multiple dependency deficiencies. Applicant's amendment in Paper No. 6, filed on 6/15/2001 presented amended claims 5-7, 10, and 14 which were then examined on the merits. The obviousness-type double patenting and 35 U.S.C. § 103 rejections which applied to claims 1-4 as originally filed (see Paper No. 5, mailed on 3/13/2001) also applied to amended claims 5-7, 10, and 14. The "new grounds of rejections" applied to amended claims 5-7, 10, and 14 because these rejections were not made in the first Office Action (Paper No. 5) due to

improper multiple dependency. Since a detailed explanation of these rejections had already been presented in a previous Office Action (Paper No. 5), the finality of the rejection is deemed proper.

4. Applicants argue that the previous Examiner of record used impermissible hindsight to combine the prior art of record. Applicants allege that the instant application does not claim the molecule set forth in SEQ ID NO: 3 but rather a system for the expression of the molecule set forth in SEQ ID NO: 3 and homologs of said molecule. Furthermore, Applicants argue that it would have not been obvious to one of skill in the art to express the protein of SEQ ID NO: 3 or homologs thereof, in *Pichia Pastoris* at the time the invention was made due to the unpredictability in the art in regard to successful expression of recombinant proteins in different hosts. Applicants also submit a reference by Ratner (Bio/Technology 7:1129-1133, 1989) as evidence of the state of the art in regard to the unpredictability of successful heterologous protein expression in yeast. Applicants argue that the success of the instant invention goes against other prior knowledge not cited by the previous Examiner of record and that the invention should be considered novel and nonobvious over the prior art of record.

5. The request for consideration in Paper No. 8, filed on 2/13/2002, under 37 CFR 1.116 in reply to the Advisory Action mailed on 1/2/2002 has been considered but is not deemed to place the application in condition for allowance for the following reasons.

6. Applicants have not provided evidence as to where impermissible hindsight was used. The references cited were valid prior art references. In addition, the motivation to combine these references as well as why one of skill in the art would have a reasonable expectation of success has been discussed in previous Office Actions. Applicants do not provide any evidence or

arguments as to why one of skill in the art would have not been motivated to combine the teachings of U.S. Patent No. 5,827,683 in view of Martinez, Tang et al. in view of Stroman et al., or the teachings of Tang in view of Martinez et al., or any unpredictability from such combinations, to arrive at the claimed invention.

7. It should be noted that the Ratner reference was published 6 years before the earliest priority date claimed by the instant application (1995). While Ratner in 1989 teaches that expression systems are protein specific and that the benefits of using *P. Pastoris* have yet to be proven (page 1131, lines 12-17), the prior art of record clearly shows not only motivation to combine the cited references but also a reasonable expectation of success. Specifically, as indicated in previous office actions, in view of Martinez et al., which teaches the benefits of using *P. pastoris* versus *S. cerevisiae* in the expression of an eukaryotic protein and the high yields obtained when *P. pastoris* was used. Applicant's arguments in regard to unpredictability due to low expression of the instant protein in *S. cerevisiae* are not persuasive due to the fact that Martinez et al. teaches the drawbacks of using *S. cerevisiae* and shows the benefits of the *P. pastoris* system. The invention as a whole would have been prima facie obvious to a person of skill in the art at the time the invention was made in view of the cited prior art of record. Therefore, Applicants have not overcome the obviousness-type double patenting and 35 USC § 103 rejections set forth in the previous Office Actions.

8. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the

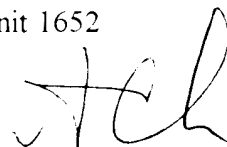
Art Unit: 1652

original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652



PA-1
SUPERVISOR

DR
February 28, 2002